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09/924,556	08/09/2001	Stephen A. Yencho	032405-058	5402

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EXAMINER
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BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/924,556

Applicant(s)

YENCHO ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002 and 18 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30-84 is/are pending in the application.
- 4a) Of the above claim(s) 30-36 and 59-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-58 and 77-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 30-36 and 67-76, drawn to an anastomosis device, classified in class 606, subclass 153.
  - II. Claims 37-58 and 77-84, drawn to an anastomosis tool for delivering an anastomosis device, classified in class 606, subclass 167.
  - III. Claims 59-66, drawn to an anastomosis system, classified in class 606 subclass 151.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as a vessel punch. See MPEP § 806.05(d).
3. Inventions III and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the particulars of the anastomosis device are not claimed in the combination. The subcombination has separate utility such as an anastomosis device that is delivered by hand.
4. Inventions III and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has

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utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the side hole. The subcombination has separate utility such as a surgical punch.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Brian Schar on September 25, 2003 a provisional election was made without traverse to prosecute the invention of group II, claims 36-42, 56-67. Affirmation of this election must be made by applicant in replying to this Office action. Claims 30-35, 43-55, 68 and 69 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the term "translatable" is not described in the specification.

### ***Double Patenting***

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in

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this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Claims 77-84 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 60-67 of copending Application No. 09/886074. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 37-43 and 55-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-42 and 56-59 of copending Application No. 09/886074. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim an anastomosis tool comprising first and second tubes, wherein one of the tubes has a side hole (claims 37-43), an anastomosis tool including a vessel penetrating member (claims 55-58).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 47, 48, 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the limitation “translatable with respect to the first tube” defines. The term translatable is not understood.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 37, 41-45, 49 and 82-84 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,024,748 to Manzo et al.

Regarding claims 37 and 45, Manzo discloses an anastomosis device applicator comprising a first tube configured to receive an anastomosis device (FIG. 19 unit 16); a second tube concentric with the first tube (tube 46), the first and second tubes configured for movement with respect to one another (FIG. 19 and 20); and a side hole in at least one of the first and second tubes configured to allow the graft vessel to pass out the side of the

tube (FIG. 19 IMA), wherein the applicator has a pre-deployment configuration where at least one tube extends beyond the distal end of the device (FIG. 19).

Regarding claim 41, Manzo discloses that the first tube is configured for removable connection to the anastomosis device (Column 8 lines 45-57).

Regarding claim 42, Manzo discloses that the anastomosis applicator further comprises a handle connected to the first and second tubes with a mechanism for deploying the anastomosis device (handle 12).

Regarding claims 43 and 84, Manzo discloses that the first tube includes a plurality of connecting members at a distal end and the anastomosis device includes a plurality of features arranged to removably connect to the plurality of connecting members (FIG. 7 indentations for curves of the clips).

Regarding claims 44 and 49, Manzo discloses an anastomosis device configured for connecting a graft vessel to a target vessel (FIG. 39).

Regarding claim 82, Manzo discloses a method of performing an anastomosis comprising the steps of receiving an anastomosis device on an anastomosis device applicator including a first and second tube; connecting a graft vessel to the anastomosis device on the anastomosis device applicator with an end of the graft vessel passing out a side hole of at least one of the first and second tubes; and deploying the anastomosis device with the anastomosis device applicator (FIGS. 19-23).

Regarding claim 83, Manzo discloses that the step of deploying the anastomosis device is performed by moving the first and second tubes with respect to one another (FIG. 19 and 20).

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17. Claims 37 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,833,698 to Hinchliffe et al.

Regarding claim 37, Hinchliffe discloses an anastomosis device applicator comprising a first tube configured to receive an anastomosis device; a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another; and a side hole in at least one of the first and second tubes configured to allow the graft vessel to pass out the side of the tube (FIG. 12).

18. Claims 45, 46, 49-51, 54-58 and 77-81 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,976,178 to Goldsteen et al.

Regarding claims 45, Goldsteen discloses an anastomosis device applicator (FIG. 7a) comprising a first tube configured to receive an anastomosis device (440); a second tube concentric with the first tube (410), the first and second tubes configured for movement with respect to one another (FIG. 15 and 17); wherein the applicator has a pre-deployment configuration where at least one tube extends beyond the distal end of the device (FIG. 15).

Regarding claims 46 and 51, Goldsteen discloses that the second tube is rotatable with respect to the first tube (Column 13 lines 1-5).

Regarding claims 49, 54 and 81, Goldsteen discloses that the anastomosis device is configured for connecting a graft vessel to a target vessel (FIGS. 18-19).

Regarding claims 50, 55, 56 and 57, Goldsteen discloses an anastomosis applicator comprising a first tube (440) configured for receiving a one-piece anastomosis device, a second tube (410) concentric with the first tube, the first and second tubes configured for movement with respect to one another and configured for deployment of the anastomosis device; a vessel penetrating member (412) configured for incision of the target vessel; and



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wherein the applicator is configured to maintain contact with the target vessel from the time of incision through complete deployment of the anastomosis device (FIGS. 18-22b).

Regarding claims 58 and 80, Goldsteen discloses that the vessel penetrating member is configured for positioning inside the concentric tubes (FIG. 15).

Regarding claim 77 and 79, Goldsteen discloses a method comprising: receiving a one-piece anastomosis device on an anastomosis device applicator having a vessel penetrating member (412); connecting a graft vessel to the anastomosis device on the anastomosis device applicator; penetrating a target vessel with the vessel penetrating member of the anastomosis device applicator; advancing the anastomosis device into the penetration in the target vessel; and deploying the anastomosis device with the anastomosis device applicator (FIGS. 18-22b).

Regarding claim 78, Goldsteen discloses that the step of deploying the anastomosis device is performed by moving two tubes of the anastomosis device applicator with respect to one another (FIGS. 18-22b).

19. Claims 50, 51, 54, 77, 78, 80 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,695,504 to Gifford, III et al.

Regarding claims 50, Gifford discloses an anastomosis applicator comprising a first tube (124) configured for receiving an anastomosis device, a second tube (125) concentric with the first tube, the first and second tubes configured for movement with respect to one another and configured for deployment of the anastomosis device (FIG. 5a-5f); a vessel penetrating member configured for incision of the target vessel (136); and wherein the applicator is configured to maintain contact with the target vessel from the time of incision through complete deployment of the anastomosis device (FIG. 5b-5e).

Regarding claim 51, Gifford discloses that the second tube is rotatable with respect to the first tube (Column 18 lines 13-20).

Regarding claims 54 and 81, Gifford discloses that the anastomosis device is configured for connecting a graft vessel to a target vessel (FIG. 5g).

Regarding claim 77, Gifford discloses a method comprising : receiving a one-piece anastomosis device on an anastomosis device applicator having a vessel penetrating member (136); connecting a graft vessel to the anastomosis device on the anastomosis device applicator; penetrating a target vessel with the vessel penetrating member of the anastomosis device applicator; advancing the anastomosis device into the penetration in the target vessel; and deploying the anastomosis device with the anastomosis device applicator (FIG. 5b-5g).

Regarding claim 78, Goldsteen discloses that the step of deploying the anastomosis device is performed by moving two tubes of the anastomosis device applicator with respect to one another (FIG. 5b-5g).

Regarding claim 80, Goldsteen discloses that the vessel penetrating member is configured for positioning inside the concentric tubes (FIG. 4).

### ***Conclusion***

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,007,576 to McClellan

U.S. Patent No. 6,241,743 to Levin et al.

U.S. Patent No. 6,293,955 to Houser et al.

U.S. Patent No. 6,371,964 to Vargas et al.

U.S. Patent No. 6,428,550 to Vargas et al.

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WO 02/30172 to Loshakove et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9302 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

*JB*  
*itb*

September 30, 2003

  
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